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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,157	07/13/2000	Niraj A. Shah	ACS-52045	4747

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EXAMINER	
WEBB, SARAH K	
ART UNIT	PAPER NUMBER
3731	8

DATE MAILED: 04/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/615,157	SHAH ET AL.
	Examiner	Art Unit
	Sarah K Webb	3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "a sheath attached to the guide wire near its distal end" in line 4. It is unclear whether "its" is referring to the sheath or the guide wire. Therefore, this limitation can be interpreted in different ways: 1) The distal end of the sheath is attached anywhere along the guide wire; 2) Any part of the sheath is attached to the distal end of the wire.

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-14,16,22,23,25, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,391,044 to Yadav et al.

Yadav discloses an embodiment of a filter delivery device in Figures 12 and 13 that includes all the limitations of claim 1. The device includes a guide wire (148), sheath (140), tubular shaft (142), and filtering assembly (144). The distal end of the sheath (140) is attached to the distal end (146) of the guide wire (148), while the proximal end of the sheath receives the filter. The distal tip (146) is interpreted to be part of the guide wire (148). The shaft (142) is positioned coaxially positioned around the guide wire (148), and as shown by the illustrations,

the shaft moves relative to the guide wire. The filter (144) is attached to the shaft (142). The filter is shown in the collapsed position in Figure 12, and is constricted in the sheath. Figure 13 illustrates the filter in an expanded position and released from the sheath.

Regarding claim 2, the filter membrane (144) is attached to spines (152), or "splines" (column 8, line 17). Figure 3 illustrates that the splines of the filter assembly are annularly spaced. Regarding claims 5 and 25, the filter assembly is inherently self-deploying, because Yadav explains that the splines cause the filter to "release" as the sheath is removed (column 8, line 17). Yadav also teaches that the splines of the filter assembly can be made of nitinol, which is a shape memory, self-expanding material (column 6, line 22). Yadav also explains that the material of the filter membrane should be permeable to allow blood flow, but also be able to capture emboli (column 8, lines 50-52).

Regarding claim 4, the filter and shaft become disposed within the sheath simultaneously as the sheath is moved proximally.

Regarding claim 7, the tubular shaft does comprise a recess that houses the splines in the unexpanded position.

Regarding claims 8 and 12, the sheath can be made of a polymeric material (column 8, line 46), which is inherently flexible. Regarding claims 16 and 26, Yadav explains that the tubular shaft may be made of polymer, stainless steel, or **nitinol** (nickel titanium alloy) (column 5, lines 19-22). Nitinol is capable of withstanding buckling. The tubular shaft is inherently a "hypotube", since it is sized for hypodermic use.

3. Claims 1,5,9,10,14,15,17,18,22 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,290,710 to Cryer et al.

Cryer discloses a filter device that includes a sheath (26) attached to the distal end of a guide wire (14), a shaft (16) disposed coaxially over the guide wire, and a filter (24) attached to the shaft (16). The filter is constrained within the sheath and expanded when released from the sheath (column 3, line 13). Regarding claim 15, the proximal end of the sheath (26) is clearly flared outward (column 6, lines 48-51). Cryer explains that the filtering element is self-expanding (column 3, lines 5-9). Regarding claim 17, Figure 4 shows that the filter device can be used in conjunction with a stent delivery mechanism (15). The entire procedure, including all the steps of claim 17, is described in line 59 of column 4 through line 22 of column 5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 19,20,21,23,25,and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cryer in view of Yadav.

Cryer includes all the limitations of claims 19,2l, and 26, except for forming the tubular shaft (16) as a hypotube that can withstand buckling. Yadav teaches that a tubular shaft that functions to carry a filter assembly can be formed as a metal hypotube (column 5, lines 19-22). Stainless steel and nitinol are inherently capable of withstanding buckling. It would have been

obvious to one of ordinary skill in the art at the time the invention was made to form the shaft of Cryer as a metal hypotube, as taught by Yadav, as this is just an alternate material for forming a shaft that carries a filter assembly.

Cryer includes all the limitations of claims 20,23, and 25, except for forming the filter assembly as a plurality of splines that are covered by a membrane. Cryer does form the filter to be self- expanding (column 3, lines 5-9). Yadav teaches that a self-expanding filter assembly can be formed as a plurality of nitinol splines covered by a membrane. The splines are resilient and withstand buckling, and the membrane allows fluid to pass through while capturing emboli. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the filter of Cryer as a plurality of splines covered by a membrane, as taught by Yadav, as this is just another way to form a self-expanding filter assembly.

5. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yadav in view of US Patent No. 5,108,419 to Reger et al.

Yadav includes all the limitations of claim 24, except for a plurality of recesses to receive the splines when the filter assembly is collapsed. Yadav does include a continuous recess in the shaft for receiving the splines, but fails to form a *plurality* of recesses. Reger discloses a filter device with splines, as shown in Figure 14. Reger teaches that a tubular shaft (180) can have a structure for receiving splines (184) that is formed as a plurality of recesses (182), as shown in Figure 17. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the spline-receiving structure of Yadav as a plurality of recesses, as taught by Reger, as this is just a substitute for the singular recess of Yadav.

Response to Arguments

6. Applicant's arguments filed 1/27/03, with respect to the rejection(s)of claim(s) 1-21 under 102 and 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of US 6,391,044 to Yadav et al. and US 6,290,710 to Cryer et al. The claimed structures are discloses in these references, as clearly explained above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 305-7554. The examiner can normally be reached on 8am-4:30pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Sarah K Webb
Examiner
Art Unit 3731

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April 9, 2003

Michael Milano
Supervisory Patent Examiner
Art Unit 3731